UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re: Bair Hugger Forced Air Warming Products Liability Litigation	MDL No. 2666 (JNE/FLN)
This Document Relates to **ALL ACTIONS**	

REPLY IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF PLAINTIFFS' ENGINEERING EXPERTS DANIEL KOENIGSHOFER, MICHAEL BUCK, SAID ELGHOBASHI, AND YADIN DAVID

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INTRODUCTION

In Plaintiffs' defense of their engineering experts' opinions and testimony, Plaintiffs concede four major points. It is now undisputed that:

- Dr. Scott Augustine authored Plaintiffs' causation theories and orchestrated the eight flawed studies that provide the core support for Plaintiffs' engineers' opinions.
- Augustine-funded researchers made several attempts to find increases in airborne bacteria associated with the Bair Hugger system, found none, and buried the results.
- Plaintiffs' engineers made no attempt to find bacteria in or around the Bair Hugger system, or to demonstrate an increase in airborne bacteria during its operation.
- Plaintiffs' computer simulation of the purported effects of the Bair Hugger system on operating room airflow was not based on real-world measurements and was not validated by a real-world experiment.

These fundamental flaws doom Plaintiffs' general causation theories, which lack the "indicia of reliability" that *Daubert* demands. *See Polski v. Quigley Corp.*, 538 F.3d 836, 840–41 (8th Cir. 2008) (affirming exclusion of expert testimony that "relied on an unproven and indeed untested premise").

Plaintiffs refer to their engineers' opinions as "bricks," Pl. Opp. Mem. at 53–54, but these "bricks"—comprising the fraudulent Augustine studies, Mr. Buck's irrelevant particle counts, and Plaintiffs' exaggerated computer model—cannot pave the way to

general causation. Because Plaintiffs' engineers have failed to establish the validity of their general causation theories, they fail to meet *Daubert*'s twin mandates of reliability and relevance, and they also fall short of *Frye-Mack*'s requirements for general acceptance and foundational reliability. Their testimony should therefore be excluded.

I. DR. AUGUSTINE'S FRAUDULENT RESEARCH IS AT THE HEART OF PLAINTIFFS' CAUSATION THEORIES.

Plaintiffs take offense at the very mention of Dr. Augustine, yet their engineering experts have embraced his work as their own. Each of their opinions traces directly to the two causation theories—"Airflow Disruption" and "Reservoirs of Infection"—that Augustine devised, and the eight studies he instigated to support them. Moreover, as the Court has already seen, Dr. Augustine and his general counsel Randy Benham were the principal authors of the playbook that Plaintiffs continue to use to this day.

Augustine and Benham helped launch this litigation by drafting a "detailed guide to suing 3M/Bair Hugger for orthopedic implant infections."[1] They planned to distribute the "Litigation Guide" to "plaintiffs' firms around the country who express an interest in jumping on this bandwagon."[2] The "Guide to Product Liability Litigation" that Augustine and Benham ghost-wrote for Plaintiffs' counsel presents the two causation theories—"Reservoirs of Infection" and "Airflow Disruption"—that Plaintiffs' engineers espouse in their opinions and testimony.[3]

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[1] AUGUSTINE_0035522-23 (DX73).

[2] *Id.*

[3] *See* AUGUSTINE_0035545–573 (DX74) at AUGUSTINE_0035555, 61.

After receiving the Guide, Plaintiffs' counsel expressed concern to Augustine and Benham about "the detailed connection between myself, the litigation and you guys."[4] Plaintiffs' counsel told them "I think we need to work towards 'sanitizing' this"[5]—much like Mark Albrecht asked his co-author Oliver Kimberger for "a little help sanitizing" the Reed "crud and bug" manuscript to remove traces of Augustine's involvement. In response, Benham removed references to "Scott as a direct source," but left the "various science sections" intact.[6] In this manner, Plaintiffs' counsel wholly and uncritically accepted Augustine's version of the "science," including the studies concocted by Augustine himself.

There is no escaping the Augustinian origins of Plaintiffs' general causation case. The Litigation Guide's references for the "Reservoir of Infection" theory are Albrecht's three "crud and bug" papers—Albrecht (2009), Albrecht (2011), and Reed (2013).[7] Its discussion of "Airflow Disruption" centers on the McGovern, Legg, Belani, and Dasari papers, all of which were spearheaded by Albrecht at Augustine's direction.[8] These same papers form the spine of Plaintiffs' Master Long Form Complaint. And it is no coincidence that Plaintiffs' engineers rely on them so heavily—even today, four years after the latest

[4] AUGUSTINE_0035526-27 (DX75)

[5] *Id.*

[6] *Id.*

[7] AUGUSTINE_0035545–573 (DX74) at AUGUSTINE_0035564.

[8] *See id.* at AUGUSTINE_0035556–59.

one was published, the Augustine/Albrecht papers continue to provide the core support for Plaintiffs' causation theories.

The problem with Plaintiffs' engineers' reliance on Augustine's work is not just the obvious financial bias behind it. The bigger problem is the fraud inherent in every one of the eight studies. Augustine-supported researchers tried to associate airborne bacteria with the Bair Hugger system on several occasions, using a variety of techniques, and every time they failed. Def. Mem. at 6, 9, 13–14. None of these negative results was ever published. Yet *every one* of the eight Augustine-orchestrated papers—including those authored by the same researchers who conducted the aerobiology experiments—suggests that the Bair Hugger system increases the risk of surgical infections. *Id.* at 5–6, 9, 13–14. The Augustine study authors raised the specter of airborne bacterial contamination, while concealing that they had already dispelled it.

The analytical chasm between Augustine's secret aerobiology findings and the conclusions urged by the Augustine study authors is far too wide to support a reliable expert opinion. *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."). Plaintiffs are forever indebted to the fraudulent work that Augustine and Albrecht churned through their "Publication Factory" between 2009 and 2013—indeed, they continue to cite them in their opposition to this motion. *See*, *e.g.*, Pl. Opp. Mem. at 8 n. 22, 23. Plaintiffs' engineers' opinions and testimony embracing Augustine's causation theories must therefore be excluded as fundamentally unreliable.

II. PLAINTIFFS' ENGINEERS HAVE FAILED TO ESTABLISH THE SCIENTIFIC RELIABILITY OF THEIR CAUSATION THEORIES.

A. Plaintiffs' Engineers Must Show That Their Hypotheses Have Been Tested.

Plaintiffs argue that "*Daubert* does not expressly require testing, just testability," Pl. Opp. Mem. at 14, but numerous cases in the 8th Circuit and elsewhere have excluded causation theories for lack of testing. *See, e.g.*, *Polski v. Quigley Corp.*, 538 F.3d 836, 840–41 (8th Cir. 2008) (affirming exclusion of expert testimony that "relied on an unproven and indeed untested premise"); *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 423 (S.D.N.Y. 2005) (excluding jexpert causation testimony because "[t]he theory that Rezulin can cause a liver injury silently never has been tested"); *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 559 (W.D. Pa. 2003) ("[S]ome reliable evidence of adequate testing of their hypothesis that Parlodel® causes ICH is required"); *Castellow v. Chevron USA*, 97 F. Supp. 2d 780, 798 (S.D. Tex. 2000) (excluding plaintiffs' experts' causation opinions because "their particular hypothesis in this case has not been subjected to testing or peer review"); *In re Accutane Prods. Liab. Litig.*, 511 F. Supp. 2d 1288, 1296 (M.D. Fla. 2007) (granting summary judgment based in part on plaintiffs' expert's failure to test or prove his "three possible mechanisms"); *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 430 (S.D.N.Y. 2016) (excluding expert testimony because "[n]o testing of the hypothesis was conducted"); *Golod v. La Roche*, 964 F. Supp. 841, 860 (S.D.N.Y. 1997) (excluding Plaintiffs' expert's causation theory because "[t]here is no

evidence that the hypothesis has been formally tested by clinical trials, in animal studies, or otherwise.").[9]

Moreover, the key fact underlying Plaintiffs' causation theories—whether the Bair Hugger system causes bacteria to reach the surgical site—*has* been tested, just not by Plaintiffs' engineers. For more than 25 years, researchers have studied whether bacteria increase over the surgical site during use of the Bair Hugger system, and all of them have found *no meaningful increase*. *See, e.g.*, Zink et al. (1993) (DX62) ("No significant difference in the total number of bacterial colonies isolated on culture plates was observed between the two study periods."); Huang et al. (2003) (DX66) ("The results showed not only that there was no increase in bacterial counts at the study sites, but also that there was a decrease … in air bacterial content around the patient and in the operating theatre."); Moretti et al. (2009) (DX67) ("[T]he mean bacterial load was numerically lower . . . after application of the Bair Hugger than immediately after placement of the patient on the operating table."). The accumulation of published and unpublished negative test results may have convinced Plaintiffs and their experts that they too would be unable to find bacteria, and that they should opt instead for a "surrogate" argument based on Buck's particle counts. But that strategy requires the factfinder to make a string of inferences that

[9] Plaintiffs' reference to an unpublished opinion from this District, *Holverson v. ThyssenKrupp Elevator Corp.*, No. 12-2765 ADM/FLN, 2014 WL 3573630 (D. Minn. July 18, 2014), is consistent with the principle that causation opinions should be based on testing. In *Holverson*, the plaintiff's expert was allowed to testify based on the *defense expert's testing* of the plaintiff's theory. *Id.* at *9.

are not only contradicted by the negative bacteria studies, but lack scientific support from the very studies Plaintiffs cite.

B. Plaintiffs' Inferential Arguments Do Not Validate Their General Causation Theories.

Plaintiffs urge the Court to infer that the Bair Hugger system is capable of causing surgical infections from the mere fact that it moves air. The Court has already observed that "[t]here is *no reasonable inference* that could be drawn by a factfinder that presence of bacteria in the device would result in an increased infection risk of the surgical site itself."[10] This applies *a fortiori* to Plaintiffs' "Airflow Disruption" theory: there is no reasonable inference that the presence of particles in operating room air increases infection risk when the device is used. Again, *Daubert* requires more than an inference; Plaintiffs' causation theories must be validated by testing.

Plaintiffs' only real-world tests are Mr. Buck's particle-counting experiments. Plaintiffs seek to leverage Buck's results by arguing that bacteria naturally follow particles, Pl. Opp. Mem. at 17–20, but Buck made no effort to *actually correlate* the two (or indeed to find bacteria at all). Moreover, the weight of the published literature is against any reliable correlation between particle counts and colony-forming units. According to a 2016 review, only two articles claim such a correlation.[11] One of them is the Stocks study, in which the authors were careful to note that "[t]he precision of predicting CFU/m^3 counts

[10] ECF No. 629 at 17.

[11] Mora M. et al. (2016), ECF No. 878-4 at 6.

from particulate count was limited."[12] The Darouiche article, published earlier this year, is equally unpersuasive because his analysis included tens of thousands of particles that were too small to be bacteria.[13] Stocks emphasized that submicron particles should be ignored when assessing airborne bioburden: "[s]maller particles are present in much higher numbers than larger ones, so monitoring particles without discriminating for size ranges obscures identification of the larger particles that may be carrying microbes."[14] Darouiche's inclusion of tens of thousands of tiny irrelevant particles renders his "correlation" suspect and unreliable.

Finally, Plaintiffs' engineers have not shown that any level of particles is a reliable predictor of the real issue in this case— infection risk. "[A]n expert must . . . explain how laboratory results will *reliably predict* effects in living humans." *In re Prempro Prods. Liab. Litig.*, 738 F. Supp. 2d 887, 894 (E.D. Ark. 2010) (emphasis added). Neither Stocks nor Darouiche provides any basis for such a prediction. The circumstances are the same as those in *Glastetter*, where the Eighth Circuit rejected plaintiffs' attempt to establish causation by extrapolating from an "intermediate fact." In *Glastetter*, the Plaintiffs' experts opined that the drug Parlodel can cause stroke based on animal studies showing that it constricted blood vessels. *Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 991 (8th Cir. 2001). The Eighth Circuit held that the experts' extrapolation from

[12] Stocks G. et al. (2010), ECF No. 735-3 at 202.

[13] *See* Darouiche R. et al. (2017), ECF No. 735-5 at 7 Table 2 (displaying "total particulate" counts).

[14]ECF No. 735-3 at 203.

vasoconstriction to stroke was unreliable, and excluded their testimony on that basis. *See id.*

Plaintiffs' engineers are trying to make the same leap that the Eighth Circuit rejected in *Glastetter*: lacking any test data to show that the Bair Hugger system sends bacteria to the surgical site, they urge the inference that particle counts are somehow enough to show an increased risk of infection. The Court should reject this unsupported extrapolation. The "analytical gap" between stirring the air and causing infections is simply too great. *Cf. Joiner*, 522 U.S. at 146.

C. Plaintiffs Distort the Literature on Particles and Bacteria.

In urging the Court to infer that "particles = bacteria = infections," Plaintiffs misrepresent much of the pertinent literature. Plaintiffs claim that "Moretti et al. . . . demonstrated an increased bacterial load in an OR when the Bair Hugger was in use, as compared to when the OR was at rest" (Pl. Opp. Mem. at 5), but they neglect to point out that the Bair Hugger system actually *reduced* airborne bacteria levels by a third to a half in that study.[15] Plaintiffs also cite a recent study by Oguz et al. for the proposition that "the presence of the Bair Hugger increased the bacterial load at the surgical site by 55%," but as Defendants noted in the opening brief, Oguz found "it was not possible to detect any higher bacterial counts on any [of the agar plates] in the forced air warming [Bair Hugger] group versus the resistive warming [HotDog] group." Def. Mem. at 45.

[15] Moretti B. et al. (2009) (ECF No. 810-2 at 218). Figure 2 shows that bacteria levels were approximately 40 CFUs/m^3 in procedures that used the Bair Hugger, vs. 60 to 80 CFUs/m^3 in procedures where it was not used. *Id.*

Plaintiffs also refer to a 3M-funded study that they claim "used particles as a proxy for bacteria" and "confirmed that particles increased over the surgical site when the Bair Hugger is turned on." Pl. Opp. Mem. at 5, 18. These characterizations are highly misleading. The study sought to determine whether an operating room laminar flow system could still meet the rigorous German "DIN" standard for particle reduction with the Bair Hugger on.[16] The DIN standard measures how well a laminar flow system reduces a large number of artificially introduced sub-micron particles (approximately 1 million per cubic foot—far more than would occur during a typical surgery).[17] Contrary to Plaintiffs' suggestion, the DIN standard doesn't have anything to do with correlating particles and bacteria, and the study made no attempt to do so.

The study showed that the Bair Hugger system does not affect the ability of a laminar flow system to meet the DIN standard for particle reduction.[18] To meet the DIN standard, a laminar system must reduce the number of artificially introduced particles by at least 100 fold (or "2 log").[19] The experiments were run with the Bair Hugger off, blowing ambient air, and blowing warmed air (as it would during surgery); in all three settings, the laminar flow system easily reduced the number of particles by more than 100 fold.[20] Plaintiffs like to point out that there was a slight increase in particles when the Bair

[16] Sessler D. et al. (2011) (ECF No. 932-4).

[17] *Id.* at 1418.

[18] *Id.* at 1416 ("Our results . . . indicate that forced-air warming does not reduce operating room air quality during laminar flow ventilation.")

[19] *Id.* at 1418.

[20] *Id.* at 1418 Figs. 2, 3.

Hugger system was turned on, but the number of particles *decreased* when the warming unit was switched from blowing room air to warmed air[21]—which completely contradicts Plaintiffs' theory that warm air currents from the blanket are responsible for transporting particles over the surgical site.

Finally, Plaintiffs attempt to bolster their causation theories with company documents and witness testimony lifted out of context. This is a misguided effort from the start: general causation evidence should come from scientific literature, not soundbites. *See In re Mirena IUD*, 169 F. Supp. 3d at 426 ("The statements and public positions of Bayer are not scientific literature that an expert would be expected to confront in the exercise of intellectual rigor in the field."); *see also Glastetter*, 252 F.3d at 991 (8th Cir. 2001) (determining that statements excerpted from company memoranda did not "admit" general causation).

Plaintiffs' cited examples demonstrate why purported "admissions" do not provide a reliable foundation for expert opinions. Mr. Van Duren agreed that the Bair Hugger was associated with increased particle counts, but as the preceding discussion shows, particle counts *decreased* when the Bair Hugger warming unit was switched from ambient to warm, which flatly contradicts Plaintiffs' "Airflow Disruption" theory. Plaintiffs also cite a draft pre-warming study protocol, Pl. Opp. Mem. at 3–4, but they never questioned any 3M or Arizant witnesses about that document. Plaintiffs should not be allowed to inject company documents lacking any foundation into these *Daubert*/Summary Judgment proceedings.

[21] *See id.* at 1418 Fig. 3.

See In re Accutane, 511 F. Supp. 2d at 1297 (excluding expert testimony based on "admissions" in company documents; expert "had no idea how they were created, why they were created, or in what context the words were used in the documents").

III. PLAINTIFFS' DEFENSES OF THEIR ENGINEERS ARE UNAVAILING.

A. Mr. Koenigshofer's Opinions Are Unqualified and Unsupported.

Mr. Koenigshofer intends to testify that the Bair Hugger's filters are inadequate, and that "[t]he hot air from the Bair Hugger will interfere with the downward flow of clean air."[22] But Koenigshofer did no testing to support either opinion, and Plaintiffs have now withdrawn his hopelessly flawed calculation that the Bair Hugger blows "at least 300 CFU [per hour] . . . near the patient." Thus, the only remaining question is whether Koenigshofer's general experience as an HVAC engineer provides any scientifically reliable support for Plaintiffs' causation theories. It does not.

Without his "calculation," Koenigshofer has no basis other than the Augustine studies for his "Airflow Disruption" opinion. Moreover, his failure to obtain and consider 3M's MERV 14 filter test results—which are the *only* filter efficiency tests in this litigation that followed ASHRAE standard 52.2—is inexcusable. Contrary to Plaintiffs' suggestion, these tests were not conducted for purposes of this litigation, but are part of the manufacturing specifications that 3M requires of its filter supplier.[23]

[22] Koengishofer Rpt. (DX 35) at 23.

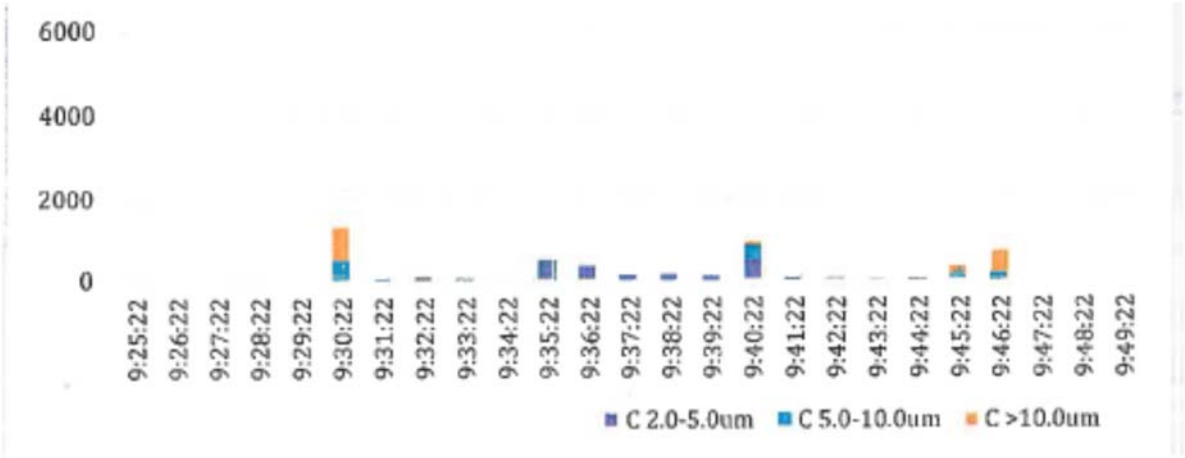
[23] Deposition of Robert Crowder, Ph.D., Corporate Representative of Pentair (DX76) at 82:5-13 (discussing "lot testing and the potential that one of the samples pulled for lot testing were to not meet [3M's] MERV 14 requirement").

Plaintiffs' defense of Koenigshofer's "common sense" opinion that particles are a proxy for bacteria also fails. He is not a microbiologist and has never conducted any bacterial sampling in an operating room. Therefore, his "common sense" view lacks expertise and is of no help to the jury. The circumstances are essentially the same as those in *Hershberger v. Ethicon Endo-Surgery, Inc.*, No. 2:10-CV-00837, 2012 WL 524442, at *8 (S.D. W. Va. Feb. 15, 2012), where the Court excluded a similar "common sense" opinion by Plaintiffs' expert Yadin David. Dr. David sought to opine that a surgical stapler that was not pre-loaded with staples was "defective." *Id.* The Court held that the opinion "does not draw on any specialized knowledge, education, or experience," and excluded it because Dr. David had no basis "to reach a more informed or helpful conclusion (than the jury) regarding what transpired in the relevant surgeries." *Id.* This Court should do the same with Mr. Koenigshofer's "common sense" testimony.

B. Mr. Buck's Experiments Are Irrelevant and Unreliable.

It bears repeating that Mr. Buck did not attempt to detect bacteria in or around the Bair Hugger system—he only counted particles. Plaintiffs agree that the only particles that could carry bacteria are those with a diameter of 10 microns or more. Pl. Opp. Mem. at 35, 54. But Plaintiffs do not address the fact that Buck found only trivial numbers of those particles in his experiments. Of the few 10-micron particles detected, almost all appeared at the beginning and end of each experiment, as shown below:[24]

[24] Buck Deposition Exhibit 9 (DX77)



This is not a coincidence. At the beginning and end of the experiments, Buck and his colleague would enter the "clean room," bringing their shed skin cells with them. Buck himself acknowledged that he and his partner could have introduced the small number of greater-than-10-micron particles in this way.[25] The experiments, and Buck's testimony about them, should be excluded as unreliable and irrelevant. They do not "fit" the facts of this case, which is fundamentally about bacteria, not particles. *Cf. Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1055 (8th Cir. 2000) (explaining Daubert's "fit" requirement); *Group Health Plan, Inc. v. Philip Morris USA, Inc.*, 344 F.3d 753, 761 (8th Cir. 2003) (excluding expert testimony that did not "fit" the proponent's case).

C. Dr. Elghobashi's Flawed Assumptions Invalidate Plaintiffs' Computer Model.

Plaintiffs' lengthy defense of Prof. Elghobashi fails to overcome two fundamental problems with his testimony: he assumed a temperature for the air around the surgical drapes that was much too high, and he did not validate the results of Plaintiffs' computer

[25] *See* Buck Depo. (DX49) at 175:3-5;177:25–178:17.

model in a real-world experiment. These failings are significant, because the temperature and velocity of the air leaving the drape determine the magnitude of the convection currents calculated by the computer model. Because Prof. Elghobashi assumed an exaggerated value, the model produced exaggerated results.

Plaintiffs attempt to justify Prof. Elghobashi's decision to *assume* a temperature by arguing that "he lacked the resources to directly measure the temperature of the air leaving the drape." Pl. Opp. Mem. at 30.[26] Apparently, Prof. Elghobashi—who charged Plaintiffs $120,000 for the computer model—elected not to acquire a hot-wire anemometer that sells for less than $200 on Amazon.[27] He could have borrowed the anemometer that Dr. David used for his experiments, in which he measured a high temperature of 36ºC (96.8 ºF) *directly under the Bair Hugger blanket*—5ºC (9ºF) lower than the temperature Elghobashi assumed for where the drape meets the floor.

Plaintiffs' argument that Elghobashi was not "legally required" to validate the computer model's results violates *Daubert*'s black-letter holding that "[p]roposed testimony must be supported by appropriate validation[.]" *Daubert*, 579 U.S. at 590.

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[26] There can be no dispute that Elghobashi made the assumption—he said it himself. Elghobashi Dep. (ECF No.932-25) at 248:8-9 ("The assumption is in the temperature of the edge of the drape"). After the deposition, Plaintiffs nevertheless tried to paper over the assumption with a supplemental report attached to Elghobashi's errata sheet. *See* Pltfs' Exhibit 31; *see also* Elghobashi errata sheet (DX78). The Court should strike the supplemental report as improper. *See Sanny v. Trek Bicycle Corp.*, CIV. 11-2936 ADM/SER, 2013 WL 1912467, at *14 (D. Minn. May 8, 2013) (striking expert errata sheet that "unquestionably reflect[ed] an attempt to bolster the substance and credibility of [the expert's] testimony" and included information "never once mentioned in the original deposition").

[27] *See* https://www.amazon.com/dp/B008SOD26Y?psc=1 (last visited October 6, 2017).

Moreover, merely validating the software code does not guarantee that the model's output will reflect what happens in the real world. One need only consult a weather forecast to appreciate the difference.

The need for validation is particularly acute where the National Institutes of Health, led by Dr. Farhad Memarzadeh, has done its own modeling of the Bair Hugger system's interaction with operating room airflow and arrived at a completely different conclusion. Elghobashi does not address the NIH's Bair Hugger findings anywhere in his report, choosing instead to attack an earlier article that "did not include the FAW blower discharge."[28] But Elghobashi's discourse on "Large Eddy Simulation" versus "Reynolds-Averaged Navier Stokes" fails to rebut the NIH's conclusion that their model "validates [the] conclusion that forced-air warming technology does not increase the risk of surgical wound infection."[29] His opinions and testimony should therefore be excluded.

D. Dr. David's General Causation Opinions Are Unqualified and Unsupported.

Despite his nearly 20 years as Director of Biomedical Engineering at the Texas Medical Center, during which he "reviewed the full array of warming modalities," Pl. Opp. Mem. at 41, Dr. David somehow avoided any substantive encounters with the Bair Hugger system—the most widely used patient-warming device in the world. This renders his "risk

[28] Elghobashi Rpt. (DX 36) at 5.

[29] Memarzadeh (2010) (DX 59).

assessment" of the Bair Hugger system automatically suspect; the suspicion is confirmed by Dr. David's denial that he conducted a clinical risk assessment at all.[30]

Dr. David is not a clinician, and his cherry-picked literature review reflects an erroneous and biased methodology. *See In re Rezulin*, 369 F. Supp. 2d at 425-26 (excluding experts who "discussed only the evidence they believed would advance the plaintiffs' position"). More importantly, Plaintiffs have not shown that Dr. David's general causation opinions are anything more than recitations from the Augustine playbook. He ignores the negative bacteria studies, and relies almost entirely on the eight Augustine/Albrecht studies.[31] His work in this case tracks what he did in *Stevens v. Stryker Corp.*, where the Court found that his report "consists of nothing but a list of regulations and conclusions that defendants violated them, along with a narrative of historical facts that does not require an expert to interpret[.]" No. 12-CV-63-BBC, 2013 WL 4758948, at *4 (W.D. Wis. Sept. 4, 2013). Dr. David's general causation opinions should therefore be excluded.

CONCLUSION

Plaintiffs' engineers did not test the one question at the heart of their general causation opinions: whether the Bair Hugger system causes bacteria to reach a patient's surgical site. Even if the Court overlooked their methodological flaws and unwarranted extrapolations, Plaintiffs' engineers' opinions amount to nothing more than a *possibility*

[30] *See, e.g.*, David Dep., ECF No. 932-30, at 278:14–279:5.

[31] David Rpt., ECF No. 316, at 27–31.

that convection currents from a warming blanket could waft particles to a surgical site. This is a far cry from demonstrating that the Bair Hugger system causes surgical infections. *See In re Accutane*, 511 F. Supp. 2d at 1296 (M.D. Fla. 2007) ("[B]iological possibility is not proof of causation."). Plaintiffs' engineers and their general causation opinions should therefore be excluded under Federal Rule of Evidence 702, *Daubert*, and *Frye-Mack*.

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Respectfully submitted,

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